

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

GLAXOSMITHKLINE
Corporate Intellectual Property
Attn. Rice, Jason N.
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Brentford
Middlesex TW8 9GS
UNITED KINGDOM

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

GLAXO GROUP LIMITED
Corporate IP
Received at BRENTFORD

- 4 JAN 2005

(PCT Rule 44.1)

ATTY JINK DV Date of mailing 11/12/2004
(day/month/year)
30/12/2004

Applicant's or agent's file reference

JNR/PB60435

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/EP2004/010654

International filing date

(day/month/year)

21/09/2004

Applicant

GLAXO GROUP LIMITED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority

 European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Maria Hoppe

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference JNR/PB60435	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2004/010654	International filing date (day/month/year) 21/09/2004	(Earliest) Priority Date (day/month/year) 23/09/2003
Applicant GLAXO GROUP LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP2004/010654

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

There is provided a medicament dispenser device comprising a housing (10) including a dispensing outlet (12) for insertion into a body cavity; a medicament discharge device (20) moveably housed within the housing (10), the medicament discharge device (20) comprising a medicament container (20) for storing the medicament to be dispensed and a medicament dispensing mechanism (22) for dispensing medicament from the container (20) to the outlet (12); a user operable actuator (50) moveable with respect to the medicament discharge device (20) to apply an actuating force to the dispensing mechanism (22); and an actuation indicator (40) responsive to application of the actuating force. A pre-load means (32,34,36) is provided to the user operable actuator (50) to prevent application of the actuating force to the dispensing mechanism (22) and actuation indicator (40) until a pre-determined threshold force is applied to the user operable actuator (50).

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP2004/010654

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M15/00 A61M15/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/020350 A (OPTINOSE AS ; DJUPESLAND PER GISLE (NO)) 13 March 2003 (2003-03-13)	1,3-5, 9-14,19, 23,26, 29-35, 47-49
A	figure 1	20,21
X	WO 99/38555 A (GOLDSTEIN & LEWIN TECH GMBH ; GOLDMANN RAUL (DE); SCHWARZWALD DETLEF) 5 August 1999 (1999-08-05)	1-3, 9-12,23, 49
A	page 7, line 22 - page 11, line 34; figure 1	15-18, 47,48
X	US 2002/117513 A1 (HEMLINGER MICHAEL) 29 August 2002 (2002-08-29)	1,3,6,7, 19-33, 47-49
A	paragraph '0029! - paragraph '0031!; figure 2	2,46
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

22 December 2004

Date of mailing of the international search report

30/12/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Kroeders, M

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/010654

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 129 786 A (BECTON DICKINSON CO) 5 September 2001 (2001-09-05) paragraph '0018! - paragraph '0031! -----	1, 3, 8, 9, 19-33, 47, 48
X	WO 01/36018 A (RASOR JULIA S ; RASOR NED S (US); CAPNIA INC (US)) 25 May 2001 (2001-05-25)	1-5, 9-14, 23, 26, 29-35, 47-49
A	page 13, line 28 - page 16, line 23; figures 8-11 -----	36-46

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/010654

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03020350	A	13-03-2003	GB 2381460 A ,B GB 2395909 A WO 03020350 A1 CA 2450492 A1 EP 1399203 A1	07-05-2003 09-06-2004 13-03-2003 03-01-2003 24-03-2004
WO 9938555	A	05-08-1999	DE 19825434 A1 AT 249854 T AU 742962 B2 AU 2510599 A BR 9814928 A CA 2319026 A1 CN 1130234 B WO 9938555 A1 DE 59809670 D1 DK 1051212 T3 EP 1051212 A1 ES 2207030 T3 HK 1034475 A1 HR 20000510 A1 HU 0100645 A2 JP 2002501791 T NO 20003847 A NZ 506050 A PL 342031 A1 PT 1051212 T SI 20363 A SK 11182000 A3 TR 200002005 T2 US 6752147 B1 ZA 9900342 A	05-08-1999 15-10-2003 17-01-2002 16-08-1999 17-10-2000 05-08-1999 10-12-2003 05-08-1999 23-10-2003 20-10-2003 15-11-2000 16-05-2004 06-02-2004 28-02-2001 28-06-2001 22-01-2002 02-10-2000 25-10-2002 21-05-2001 31-12-2003 30-04-2001 12-02-2001 21-11-2000 22-06-2004 19-05-1999
US 2002117513	A1	29-08-2002	DE 10110742 A1 EP 1236516 A2	05-09-2002 04-09-2002
EP 1129786	A	05-09-2001	US 6382204 B1 AU 6547200 A EP 1129786 A2 JP 2001137355 A US 2004025866 A1 US 2002010428 A1 US 2002035349 A1	07-05-2002 26-04-2001 05-09-2001 22-05-2001 12-02-2004 24-01-2002 21-03-2002
WO 0136018	A	25-05-2001	AU 4135801 A AU 777257 B2 AU 5931500 A CA 2375679 A1 CA 2389294 A1 EP 1218049 A2 EP 1237610 A2 JP 2004500168 T WO 0103645 A2 WO 0136018 A2 AU 7208601 A CA 2400375 A1 EP 1259282 A1 JP 2004511263 T WO 0164280 A1	30-05-2001 07-10-2004 30-01-2001 01-01-2001 25-05-2001 03-07-2002 11-09-2002 08-01-2004 18-01-2001 25-05-2001 12-09-2001 07-09-2001 27-11-2002 15-04-2004 07-09-2001

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/010654

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0136018	A	US 2002040205 A1	04-04-2002